

MEDICAL CONTESTED CASE HEARING NO. 14079

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Texas Department of Insurance, Division of Workers' Compensation. For the reasons discussed herein, the Hearing Officer determines that the claimant is not entitled to an outpatient lumbar epidural steroid injection via caudal catheter on the right at L4-5 and L5-S1, for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

A contested case hearing was held on June 27, 2014 to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the claimant is not entitled to an outpatient lumbar epidural steroid injection via caudal catheter on the right at L4-5 and L5-S1, for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by LS, an ombudsman.
Respondent/Carrier appeared and was represented by JL, attorney.

DISCUSSION

The claimant's doctor requested preauthorization for an outpatient lumbar epidural steroid injection via caudal catheter on the right at L4-5 and L5-S1. The carrier denied the request twice, and the claimant's doctor appealed. An Independent Review Organization (IRO) was appointed to settle the dispute. The IRO determined that the requested treatment was not medically necessary. The IRO decision indicates that a board-certified anesthesiologist conducted the review for the IRO. The decision also indicates that the anesthesiologist relied in part on the treatment portion of the Official Disability Guidelines (ODG) in conducting the review.

Texas Labor Code Section 408.021 provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Health care reasonably required is further defined in Texas Labor Code Section 401.011 (22a) as health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with evidence based medicine or, if evidence based medicine is not available, then generally accepted standards of medical practice recognized in the medical community. Health care under the Texas Workers' Compensation system must be consistent with evidence based medicine if that evidence is

available. Evidence based medicine is further defined in Texas Labor Code Section 401.011 (18a) to be the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts and treatment and practice guidelines.

The Commissioner of the Division of Workers' Compensation is required to adopt treatment guidelines that are evidence-based, scientifically valid, outcome-focused, and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. Texas Labor Code Section 413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable in accordance with Texas Labor Code Section 413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the Official Disability Guidelines (ODG), and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. Also, in accordance with Division Rule 133.308(s), "A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division are considered parties to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence."

With regard to epidural steroid injections, under "Epidural steroid injections (ESIs), therapeutic," the ODG reads as follows:

Recommended as a possible option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy) with use in conjunction with active rehab efforts. Not recommended for spinal stenosis or for nonspecific low back pain. See specific criteria for use below. Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, but ESIs have not been found to be as beneficial a treatment for the latter condition. According to SPORT, ESIs are associated with less improvement in spinal stenosis. (Radcliff, 2013)

Short-term symptoms: The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months. (Armon, 2007) Epidural steroid injection can offer short-term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function or return to work. There is no high-level evidence to support the use of

epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculopathy. (Benzon, 1986) (ISIS, 1999) (DePalma, 2005) (Molloy, 2005) (Wilson-MacDonald, 2005)

Use for chronic pain: Chronic duration of symptoms (> 6 months) has also been found to decrease success rates with a threefold decrease found in patients with symptom duration > 24 months. The ideal time of either when to initiate treatment or when treatment is no longer thought to be effective has not been determined. (Hopwood, 1993) (Cyteval, 2006) Indications for repeating ESIs in patients with chronic pain at a level previously injected (> 24 months) include a symptom-free interval or indication of a new clinical presentation at the level.

For spinal stenosis: The use of epidural steroid injection (ESI) in patients with lumbar spinal stenosis is common, but there is little evidence in the literature to demonstrate its long-term benefit. Despite equivalent baseline status, ESIs are associated with significantly less improvement at 4 years among all patients with spinal stenosis. Furthermore, ESIs were associated with longer duration of surgery and longer hospital stay. There was no improvement in outcome with ESI whether patients were treated surgically or nonsurgically. There was no distinct surgical avoidance noted with ESI. (Radcliff, 2013) This systematic review found the data was limited to suggest that ESI is effective in lumbar spinal stenosis. (Bresnahan, 2013) An RCT addressed the use of ESIs for treatment of spinal stenosis, and there was no statistical difference except in pain intensity and Roland Morris Disability Index and this was at two weeks only. (Koc, 2009) According to the APS/ ACP guidelines, ESIs are not for nonspecific low back pain or spinal stenosis. (Chou, 2008)

Transforaminal approach: Some groups suggest that there may be a preference for a transforaminal approach as the technique allows for delivery of medication at the target tissue site, and an advantage for transforaminal injections in herniated nucleus pulposus over translaminar or caudal injections has been suggested in the best available studies. (Riew, 2000) (Vad, 2002) (Young, 2007) This approach may be particularly helpful in patients with large disc herniations, foraminal stenosis, and lateral disc herniations. (Colorado, 2001) (ICSI, 2004) (McLain, 2005) (Wilson-MacDonald, 2005) Two recent RCTs of caudal injections had different conclusions. This study concluded that caudal injections demonstrated 50% pain relief in 70% of the patients, but required an average of 3-4 procedures per year. (Manchikanti, 2011) This higher quality study concluded that caudal injections are not recommended for chronic lumbar radiculopathy. (Iversen, 2011)

Fluoroscopic guidance: Fluoroscopic guidance with use of contrast is recommended for all approaches as needle misplacement may be a cause of

treatment failure. (Manchikanti, 1999) (Colorado, 2001) (ICSI, 2004) (Molloy, 2005) (Young, 2007)

Factors that decrease success: Decreased success rates have been found in patients who are unemployed due to pain, who smoke, have had previous back surgery, have pain that is not decreased by medication, and/or evidence of substance abuse, disability or litigation. (Jamison, 1991) (Abram, 1999) Research reporting effectiveness of ESIs in the past has been contradictory, but these discrepancies are felt to have been, in part, secondary to numerous methodological flaws in the early studies, including the lack of imaging and contrast administration. Success rates also may depend on the technical skill of the interventionalist. (Carette, 1997) (Bigos, 1999) (Rozenberg, 1999) (Botwin, 2002) (Manchikanti, 2003) (CMS, 2004) (Delpont, 2004) (Khot, 2004) (Buttermann, 2004) (Buttermann2, 2004) (Samanta, 2004) (Cigna, 2004) (Benzon, 2005) (Dashfield, 2005) (Arden, 2005) (Price, 2005) (Resnick, 2005) (Abdi, 2007) (Boswell, 2007) (Buenaventura, 2009) Also see Epidural steroid injections, “series of three” and Epidural steroid injections, diagnostic. ESIs may be helpful with radicular symptoms not responsive to 2 to 6 weeks of conservative therapy. (Kinkade, 2007) Epidural steroid injections are an option for short-term pain relief of persistent radiculopathy, although not for nonspecific low back pain or spinal stenosis. (Chou, 2008) As noted above, injections are recommended if they can facilitate a return to functionality (via activity & exercise). If post-injection physical therapy visits are required for instruction in these active self-performed exercise programs, these visits should be included within the overall recommendations under Physical therapy, or at least not require more than 2 additional visits to reinforce the home exercise program.

With discectomy: Epidural steroid administration during lumbar discectomy may reduce early neurologic impairment, pain, and convalescence and enhance recovery without increasing risks of complications. (Rasmussen, 2008) Not recommended post-op. The evidence for ESI for post lumbar surgery syndrome is poor. (Manchikanti, 2012)

Patient selection: ESIs are more often successful in patients without significant compression of the nerve root and, therefore, in whom an inflammatory basis for radicular pain is most likely. In such patients, a success rate of 75% renders ESI an attractive temporary alternative to surgery, but in patients with significant compression of the nerve root, the likelihood of benefiting from ESI is low (26%). This success rate may be no more than that of a placebo effect, and surgery may be a more appropriate consideration. (Ghahreman, 2011)

MRIs: According to this RCT, the use of MRI before ESIs does not improve patient outcomes and has a minimal effect on decision making, but the use of

MRI might have reduced the total number of injections required and may have improved outcomes in a subset of patients. Given these potential benefits as well as concerns related to missing important rare contraindications to epidural steroid injection, plus the small benefits of ESIs themselves, ODG continues to recommend that radiculopathy be corroborated by imaging studies and/or electrodiagnostic testing. (Cohen, 2012)

Fracture risk: Lumbar ESIs are associated with an increased risk for spinal fracture. Each single additional ESI increased the risk for fracture by 21%, with an increasing number of ESIs associated with an increasing likelihood of fracture. Use of ESIs seems to promote deterioration of skeletal quality. This definable fracture risk should be balanced with the best available evidence regarding the long-term efficacy of ESIs, which is limited. Clinicians should consider these findings before prescribing ESIs for elderly patients. (Mandel, 2013)

Recent research: An updated Cochrane review of injection therapies (ESIs, facets, trigger points) for low back pain concluded that there is no strong evidence for or against the use of any type of injection therapy, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy. (Staal-Cochrane, 2009) Recent studies document a 629% increase in expenditures for ESIs, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) There is fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief. (Chou3, 2009) This RCT concluded that caudal epidural injections containing steroids demonstrated better and faster efficacy than placebo. (Sayegh, 2009) In this RCT there were no statistically significant differences between any of the three groups at any time points. This study had some limitations: only one type of steroid in one dose was tested; the approach used was caudal and transforaminal injections might provide superior results. (Weiner, 2012) Effects are short-term and minimal. At follow-up of up to 3 months, epidural steroids were associated with statistically significant reductions in mean leg pain and mean disability score, but neither of these short-term improvements reached the threshold for clinical significance. There were no significant differences in either leg pain or disability at 12 months follow-up. (Pinto, 2012) According to this systematic review, ESIs without the drug (epidural nonsteroid injections), often used as a placebo treatment, were as effective as ESIs and better than no epidural injections. (Bicket, 2013) This meta-analysis suggested that ESI did not improve back-specific disability more than a placebo or other procedure long-term (6 months), and did not significantly decrease the number of patients who underwent subsequent surgery. (Choi, 2013)

Criteria for the use of Epidural steroid injections:

Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, reduction of medication use and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.

- (1) Radiculopathy (due to herniated nucleus pulposus, but not spinal stenosis) must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.
- (2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
- (3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.
- (4) *Diagnostic Phase:* At the time of initial use of an ESI (formally referred to as the “diagnostic phase” as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (< 30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections.
- (5) No more than two nerve root levels should be injected using transforaminal blocks.
- (6) No more than one interlaminar level should be injected at one session.
- (7) *Therapeutic phase:* If after the initial block/blocks are given (see “Diagnostic Phase” above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the “therapeutic phase.” Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. (CMS, 2004) (Boswell, 2007)
- (8) Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.
- (9) Current research does not support a routine use of a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 2 for therapeutic treatment.

(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.

(11) Cervical and lumbar epidural steroid injection should not be performed on the same day. (Doing both injections on the same day could result in an excessive dose of steroids, which can be dangerous, and not worth the risk for a treatment that has no long-term benefit.)

To overcome an IRO decision which denies treatment, a claimant must do *one* of the following:

1) Show that the requested treatment is consistent with the criteria set out by the Official Disability Guidelines (ODG);

2) Present evidence-based medicine that is more persuasive than the ODG. In other words, a claimant must present documentation or testimony that is based on evidence-based medicine. That documentation or testimony must show that the requested treatment is likely to be effective; or

3) Show that the requested treatment is not addressed by the ODG. In such a case, a claimant must show that the requested treatment is supported by other evidence-based medicine, or if there is no evidence-based medicine on point, a claimant must show that the requested treatment meets the generally accepted standards of medical practice recognized in the medical community.

In the instant case, the claimant asserted that the requested treatment was consistent with the criteria set out by the ODG. To support her assertion, the claimant called MB, M.D., as a witness. Dr. B testified by telephone. Dr. B opined that, based on his education, training, and experience, the requested treatment was medically necessary. Dr. B, however, did not explain how the requested treatment met the *specific criteria* set out by the ODG.

The evidence presented by the claimant on the disputed issue was not persuasive. The claimant failed to prove that the requested treatment is consistent with the specific criteria set out by the ODG.

The Hearing Officer considered all of the evidence admitted. The Findings of Fact and Conclusions of Law are based on an assessment of all of the evidence whether or not the evidence is specifically discussed in this Decision and Order.

FINDINGS OF FACT

1. The parties stipulated to the following facts:

A. Venue is proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.

- B. On (Date of Injury), the Claimant was the employee of (Employer), Employer.
 - C. On (Date of Injury), the Employer had Texas workers' compensation insurance coverage through the Texas Association of School Boards Risk Management Fund.
 - D. On (Date of Injury), the Claimant sustained a compensable injury.
 - E. The IRO determined that the claimant should not have the requested treatment.
2. Carrier delivered to Petitioner/Claimant a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.
 3. The requested treatment is not consistent with the criteria set out by the ODG.
 4. An outpatient lumbar epidural steroid injection via caudal catheter on the right at L4-5 and L5-S1 is not health care reasonably required for the compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.
2. Venue is proper in the (City) Field Office.
3. The preponderance of the evidence is not contrary to the decision of the IRO that an outpatient lumbar epidural steroid injection via caudal catheter on the right at L4-5 and L5-S1 is not health care reasonably required for the compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to an outpatient lumbar epidural steroid injection via caudal catheter on the right at L4-5 and L5-S1, for the compensable injury of (Date of Injury).

ORDER

Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **TEXAS ASSOCIATION OF SCHOOL BOARDS RISK MANAGEMENT FUND**, and the name and address of its registered agent for service of process is

**JAMES B. CROW
7703 N. LAMAR
AUSTIN, TEXAS 78752**

Signed this 8th day of August, 2014

Carlos Cerrato
Hearing Officer